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David Fox, Esq.
Office of General Counsel
Food and Drug Administration
5600 Fishers Lane
Room 689
Rockville, MD 20857

Re: Docket No. 98P-1075/CP1

Dear Mr. Fox:

I have received Jane Axelrad's June 15, 1999 response to Hoffmann-La Roche Inc.'s ("Roche's") Citizen Petition of November 27, 1998 and my letter of January 14, 1999, and appreciate the agency's attention to this matter. In its Citizen Petition, Roche requested that the Food and Drug Administration ("FDA") require that all manufacturers of ticlopidine hydrochloride implement a postmarketing safety program, including patient and professional education and free blood monitoring, to ensure the continued safe marketing of this product.

In Roche's petition, the company argued, in part, that under section 505(j)(2)(A)(v) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), generic manufacturers should be required to provide the same labeling for ticlopidine as that required of Roche. As you will recall, Roche's labeling for Ticlid (ticlopidine hydrochloride) is extensive and includes numerous educational materials for both patients and professionals. Because section 505(j)(2)(A)(v) of the FD&C Act requires that an ANDA contain "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug ... except for changes required . . . because the new drug and the listed drug are produced or distributed by different manufacturers," 21 U.S.C. § 355(j)(2)(A)(v), Roche argued that in order to have its generic drug approved, an ANDA applicant must

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demonstrate that "labeling proposed for the new drug is the same as the labeling approved for the listed drug." Roche further argued that the term "labeling," as used in § 505(j)(2)(A)(v), includes the types of educational materials provided for in a postmarketing safety program. Roche concluded that if FDA failed to require the educational materials on the part of the generics, the resulting products would not bear "the same [labeling] as the labeling approved for the listed drug. . ." and that such a failure would violate section 505(j)(2)(A)(v) of the Act, 21 U.S.C. § 355(j)(2)(A)(v).

In FDA's June 15, 1999 response, the agency indicated that while the "educational program is an important sponsor-initiated tool designed to draw attention to the risk management program described in the labeling" it was not required at the time of approval. Based on this information, Roche has concluded that for purposes of section 505(j)(2)(A)(v) of the Act the term "labeling approved for the listed drug" includes only required labeling, namely those labeling materials that have been explicitly approved by FDA as part of a New Drug Application or supplement thereto. Please let me know if this does not accurately reflect the agency's conclusion.

Ultimately, the agency's letter concludes that while "a sound educational program can enhance the safety of a product such as ticlopidine", such a program shall not be required of any manufacturer. Rather, FDA will "strongly encourage" all manufacturers to conduct such an educational program. With regard to the second component of Roche's present program, the provision of the free blood testing services, FDA concludes that the free program does not significantly enhance the safe use of the drug and that neither Roche nor any other manufacturer will be required to provide such a program.

Roche believes that the agency's June 15 letter sufficiently responds to the concerns raised in the petition and does not require a more formal response. Further, as the agency requested in its June 15 correspondence, Roche hereby withdraws its request for a meeting with the agency to discuss the issues raised in the Citizen Petition. Roche has concluded that it is not advisable at this time to withdraw its Citizen Petition. In light of this letter, however, and in order to accommodate FDA's desire to clear its citizen petition docket, Roche views this matter as resolved.

HOGAN & HARTSON L.L.P.

If you have any questions or I can be of assistance, please do not hesitate to contact me.

Sincerely yours,

Robert P Brady

Robert P. Brady
Counsel for Hoffmann-La Roche Inc.

cc: F. C. Kentz III